I. AMENDMENTS TO THE CLAIMS

There are no amendments to the claims.

Listing of Claims:

Claim 1 (original) A method of treating hemophilia, said method comprising

a) aerosolizing a Factor IX (F.IX), wherein the aerosolized F.IX:

i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm, has a fine particle fraction percent less than 3.3 μm (FPF%<3.3 μm) of at least 50%,

ii) is at least 90% monomeric,

iii) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and

iv) is a dry powder having less than 10% water (wt/wt);

b) inhaling the aerosolized F.IX and allowing the aerosolized F.IX to deposit in the lung;

c) followed by exhalation.

Claim 2 (original) The method of claim 1, wherein the MMAD is 2.8 to 3.6 μm, the FPF%<3.3 μm is at least 60%, the monomer content is at least 95% and the after-aerosolization activity/pre-aerosolization activity is at least 90%.

Claim 3 (original) The method of claim 1, wherein the MMAD is about 3-3.5 μm, the FPF%<3.3 μm is at least 64%, the monomer content is at least 97%, and the after-aerosolization activity/pre-aerosolization activity is at least 95%.

Claim 4 (original) The method of claim 1, wherein the F.IX is aerosolized without alcohol.

Claim 5 (original) The method of claim 1, wherein the F.IX is recombinant.

Claim 6 (original) The method of any of claims 1 through 5, wherein the F.IX comprises a tri-leucine excipient.

Claim 7 (original) The method of claim 6, wherein the tri-leucine/F.IX ratio is 0.5-1.5wt/wt.

Claim 8 (original) A method of treating hemophilia, said method comprising the inhalation of aerosolized, dry Factor IX (F.IX), wherein the aerosolized dry F.IX:

a) comprises a surface active di- or tri-peptide, b) has a MMAD of between 2.8-3.5 μm, c) an FPF%<3.3 μm of greater than 60%, d) a monomer content of at least 95%, e) the after-aerosolization activity/pre-aerosolization activity is at least 80%, and f) less than 10% water.

Claim 9 (original) The method of claim 8, wherein the MMAD is about 3-3.5 μm, the FPF%<3.3 μm is at least 64%, the after-aerosolization activity/pre-aerosolization activity is at least 90%; the monomer content is at least 97% and the water content is less than 5%.

Claim 10 (original) The method of claim 8, wherein the F.IX does not contain alcohol.

Claim 11 (original) The method of claim 8, wherein the F.IX is recombinant.

Claim 12 (original) The method of any of claims 8 through 11, wherein the F.IX comprises a tri-leucine excipient.

Claim 13 (original) The method of claim 6, wherein the tri-leucine/F.IX ratio is 0.5-1.5wt/wt.

Claim 14 (original) A method of preventing hemophilic bleeding in advance of a hemophilic assault, said method comprising

a) aerosolizing a Factor IX (F.IX), wherein the aerosolized F.IX:

i) has a mass median aerodynamic diameter (MMAD) of between 2 and 4 μm,

ii) has a fine particle fraction percent less than 3.3 μm (FPF%<3.3 μm) of at least 50%,

iii) is at least 90% monomeric,

iv) wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%; and

v) is a dry powder having less than 10% water (wt/wt);

b) inhaling the aerosolized F.IX at least once per week and allowing the aerosolized F.IX to deposit in the lung;

c) followed by exhalation.

Claim 15 (original) The method of claim 14, wherein the inhalation is bi-weekly.

Claim 16 (original) The method of claim 14, wherein the inhalation is every 2 to 3 days.

Claim 17 (original) A composition comprising aerosolizable dry F.IX having, when aerosolized an MMAD between 2 and 4 μm, an FPF%<3.3 μm of at least 50%, an emitted dose (ED) of at least 50%, a monomer content of at least 95%, wherein the after-aerosolization activity/pre-aerosolization activity is at least 80%, less than 10% water, and a surface active di- or tri-peptide excipient, but does not have ethanol.

Claim 18 (original) The composition of claim 17, wherein the MMAD is between 2.8 and 3.6 μm, the ED is at least 60%, the after-aerosolization activity/pre-aerosolization activity is at least 95%, the FPF%<3.3 μm is at least 65% and less than 5% water.

Claim 19 (original) The composition of claim 17, wherein the MMAD is between 3 and 3.5 μm, the FPF%<3.3 μm is at least 64%, the ED is at least 80%, wherein the after-aerosolization activity/pre-aerosolization activity is at least 95%, the monomer content is at least 97% and the water content is less than 5%.

Claim 20 (original) A blister pack containing F.IX, wherein the blister pack is waterproof and contains F.IX that is at least 90% monomeric and has less than 10% (wt/wt) water and a surface active di- or tri-peptide excipient, but does not have ethanol.

Claim 21 (original) The blister pack of claim 20, wherein the F.IX is at least 95% monomeric and has less than 5% (wt/wt) water and the excipient is a dileucyl or a tri-leucine.

Claim 22 (original) The blister pack of claim 20, wherein the F.IX is at least 97% monomeric and has less than 5% (wt/wt) water and the excipient is tri-leucine.

Claim 23 (original) The blister pack of any of claims 20 to 22, wherein the F.IX is recombinant F.IX.

Claim 24 (original) A dry powdered F.IX comprising a biologically active recombinant Factor IX that is at least 90% monomeric and has less than 10% water, and a surface active di- or tri-peptide excipient, but does not have ethanol.

Claim 25 (original) The dry powdered F.IX of claim 24, wherein the excipient is tri-leucine.

Claim 26 (original) The dry powdered F.IX of claim 25, wherein there ratio of F.IX to excipient is 0.2-5.0/1.

Claim 27 (original) A composition comprising dry, dispersible powder and a solid content of about 50 wt% glycosylated F.IX, about 40 wt% trileucine and about 10 wt% buffer.

Claim 28 (original) A composition comprising dry, dispersible powder and a solid content of 40-60 wt% glycosylated F.IX, 40-60 wt% trileucine and 0-10 wt% buffer.